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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,265	11/21/2003	David Hildebrand	50229-412	8133

7590

09/08/2005

MCDERMOTT, WILL & EMERY  
600 13th Street, N.W.  
Washington, DC 20005-3096

EXAMINER
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CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/718,265	Applicant(s) HILDEBRAND ET AL.	
	Examiner Iqbal Chowdhury, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/21/2004</u><br><u>and 11/21/2003</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application is a non-provisional application filed on 11/21/2003.

Claims 1-13 are pending.

Applicant's election with traverse of Group I, Claims 1-3 and 5-7 in the communication on 6/27/2005 is acknowledged. The traversal is on the ground(s) that there would be no burden of search for the coexamination of Groups I and Groups IV simultaneously. However, claim 8 which drawn to be a transgenic plant, is not in Group IV but in Group III. If, applicant meant Group III, which is transgenic plant, it is not found persuasive because while the search necessary for examination of the two groups overlaps it is not coextensive, examination of Group III would require search of subclasses unnecessary for the search of Group I, for example 435/252.3 and 800/295. Applicant argues that the polynucleotide and transgenic plant are not independent, as it is not shown that they are not use together. However, this is not persuasive as it is not clear how applicant believe that these independent products are disclosed as used together. While transgenic plant comprises the polynucleotides the specification does not describe the use of a polynucleotide together with a transgenic plant. Use of a transgenic plant is not a use of a polynucleotide.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4 and 8-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

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claim. Applicant timely traversed the restriction (election) requirement in the communication of 6/27/2005.

Claims 1-3 and 5-7 are at issue and are present for examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is indefinite in the recitation "nucleic acid encodes a polypeptide" which is indefinite. Read broadly, "a polypeptide of SEQ ID NO: 1" could be interpreted as including a fragments of the polypeptide of SEQ ID NO: 1. However, as this does not appear to have been applicants intent. For further examination the examiner has interpreted claim 2 as excluding this.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims 1, 5 and 6 are indefinite in the recitation "at least about 90%" which is ambiguous and confusing. It is unclear whether applicant meant "at least 90%" or "about 90%". However, "about 90%" is unclear and vague, as it is not clearly stated in the specification about what is the scope of "about 90%" mean? In addition, the combination of "at least about 90%" is ambiguous and confusing. Accordingly, claims 2-3 and 7 are rejected, as they are dependent on claim 1 and claim 6.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotide encoding an enzyme of SEQ ID NO: 1, does not reasonably provide enablement for any polynucleotide encoding a hydroperoxide lyase having 90% identity to an enzyme of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1 and 5-7 are so broad as to encompass any nucleic acid encoding hydroperoxide lyase having 90% identity to an enzyme of SEQ ID NO: 1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotide encoding hydroperoxide lyases broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one hydroperoxide lyase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all nucleic acids encoding any hydroperoxide lyase with 90% identity to the enzymes of SEQ ID NOS: 1 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting hydroperoxide lyase activity; (B) the general tolerance of hydroperoxide lyase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any hydroperoxide lyase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including nucleic acids encoding hydroperoxide lyase with an enormous number of amino acid modifications of the hydroperoxide lyase of SEQ ID NOS: 1 and 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of hydroperoxide lyase genes having the desired biological characteristics is unpredictable and the

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experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### ***Conclusion***

#### **Status of the claims:**

Claims 1-13 are pending.

Claims 4 and 8-13 are withdrawn.

Claims 1-3 and 5-7 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Iqbal Chowdhury, PhD, Patent Examiner,  
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IC, 8/16/2005

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